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*DK*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/913,555 09/19/97 KAYAGAKI

N 715-118

020277  
MCDERMOTT WILL & EMERY  
600 13TH STREET NW  
WASHINGTON DC 20005-3096

HM12/1105

EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

18

DATE MAILED:

11/05/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

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# Office Action Summary

Application No.  
**08/913,555**

Applicant(s)  
**Kayagaki, et al.**

Examiner  
**Mary B. Tung**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Jun 27, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 51-62, 73-75, and 154 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☒ Claim(s) 51-53, 55-62, 73-75, and 154 is/are allowed.

☒ Claim(s) 54 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

***Continued Prosecution Application***

1. The request filed on 9/29/99 for a Continued Prosecution Application (CPA) under 37 C.F.R. 1.53(d) based on parent Application No. 08/913,555 is acceptable and a CPA has been established. An action on the CPA follows.

***DETAILED ACTION***

2. Claims 1-50 were cancelled in the paper filed September 19, 1997 (Paper No. 3).
3. Claims 51-154 were added in Paper No. 3.
4. Non-elected claims 63-72 and 76-153 were cancelled in the amendment filed 6/29/99 (Paper No. 15).
5. Claims 51-62, 73-75 and 154 are pending.
6. Applicant's arguments filed in Paper No. 15 have been fully considered but they are not persuasive.

***Claim Rejections - 35 U.S.C. § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 54 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons set forth in the action mailed May 28, 1998.
9. The Applicants submitted a declaration by Mr. Motomi Nakata stating that "one of skill in the art could produce the Fas/WR19L cell line recited in claim 54 without the use of a deposit of the biological material." ... "using the method referenced at page 51, lines 17-26 of the present specification." The Applicants argue that one of ordinary skill in the art can obtain the Fas/WR19L cell line by following the procedure disclosed in Hanabuchi, et al., *PNAS USA*, 91:4930-4934, 1994 and simply substituting the human Fas gene and WR19L cells for mouse Fas gene and I5178Y cell and that WR19L cells are publicly available from ATCC (ATCC TIB52). However, the Examiner repeats the

argument from the action mailed 4/1/99 (Paper No. 12) that the limitations of the claim **requires the use of the Fas/WR19L cell line in particular** and due to variations in cloning procedures, insertion sites, and so forth, to obtain the particular claimed cell line would require undue experimentation by one of skill in the art to repeat reliably. Therefore, it is apparent that the Fas/WR19L cell line recited in claim 54 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of said cell line. See 37 C.F.R. 1.802. Additionally, the Applicants failed to properly incorporate by reference the Hanabuchi reference. As stated in *MPEP 608.01(p)*, the mere mention of reference is not an incorporation of the subject matter into the specification. Therefore, the Applicants are required to comply with the rules for deposit of Biological material as discussed in the action mailed May 18, 1998 and the rejection stands. Additionally, the mere incorporation by reference of the Hanabuchi article would not be sufficient to enable the claimed invention. The Hanabuchi reference does not teach making the claimed cell line, nor does it use the ATCC parent cell line used by the Applicants.

*MPEP 608.01(p)* states: **Nonessential subject matter** may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non - patent publications. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art. **Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph.** *In re de Seversky*, 474 F.2d 671, 177 USPQ 144, (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. **Also**, An application as filed must be complete in it self in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent or (2) a pending U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). **In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non - patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.** See *In re Fouché*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971).

10. Therefore, the specification must be amended to include the essential material.

#### ***Allowable Subject Matter***

11. Claims 51-53, 55-62, 73-75 and 154 are allowed.

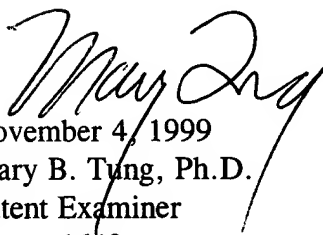
*Conclusion*


12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

  
November 4, 1999  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT ~~182~~ 1644